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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,180	07/11/2001	Keith D. Allen	R-477	1187

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[REDACTED] EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	15

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,180	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11, 13, 16 and 18-32 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11, 13, 18-26 and 28-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 October 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

This Office Action is a response to the "Amendment Under 37 C.F.R. §1.111" filed October 31, 2002(Paper No. 13) in reply to the Office Action mailed June 19, 2002 (Paper No. 11). Claims 1, 3-5, 8, 10, 11, 13, 18, 21, 23, 25 and 26 were amended, claims 12, 14, 15 and 17 were canceled and claims 28-32 were added in Paper No. 13. Claims 16 and 27 were withdrawn from consideration in Paper No. 11. Therefore, claims 1-11, 13, 18-26 and 28-32 are pending and under consideration in the application.

Election/Restrictions

This application contains claims 16 and 27 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The corrected or substitute drawings were received on October 28, 2002. These drawings are acceptable.

Response to Amendment

All rejections as they pertain to claims 12, 14, 15 and 17 are rendered moot by the cancellation of those claims in Paper No. 13.

Applicant has not supplied a clean copy of claim 11. Applicant must supply a clean copy of claim 11 with the response to this Office Action.

Claim Rejections - 35 USC § 112, first paragraph (enablement)

Claims 5-11, 13 and 18-26 stand rejected, and new claims 28-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for the full scope of the claims for the reasons set forth in Paper No. 11.

In response to the rejection, applicant has amended claims 5, 8 and 10 such that they are now directed to cells and mice, and methods of producing cells and mice, comprising a “genome comprising a target sequence disrupted by homologous recombination...with a sequence homologous to a region of SEQ ID NO:1”. Applicant argues, “the amended claims are not concerned, as the Examiner asserts...with ‘any disruption in any stefin homologue gene’” (Paper No. 13, page 5). However, the amendment is not sufficient to overcome the rejection because the claims still encompass subject matter beyond what is enabled by the disclosure. As stated in the previous Office Action, “the specification is enabling for a homozygous knockout mouse comprising a disruption in the stefin homologue gene set forth in SEQ ID NO:1 and exhibiting phenotypic features such as hyperactivity, decreased propensity to despair, schizophrenic behavior and decreased prepulse inhibition as compared to wild-type mice” (Paper No. 11, page 3). The amended claims, and the claims added in Paper No. 13, encompass products and methods comprising disruption of *any* gene that is homologous to a sequence that is homologous to a region of SEQ ID NO:1. In other words, the disrupted gene need not comprise the sequence set forth as SEQ ID NO:1, it need only be sufficiently homologous to a sequence that has some unspecified degree of homology to SEQ ID NO:1 for recombination to occur. Furthermore, the cells and animals of claims 5-9 and 28-32 need not comprise a disruption that results in a

phenotype that is enabled by the teachings of the specification. The Office Action clearly states that the disclosure is only enabling for disruption of a target gene comprising the sequence set forth in SEQ ID NO:1, wherein an animal that is homozygous for the disruption expresses a phenotype including hyperactivity, decreased propensity to despair, schizophrenic behavior and decreased prepulse inhibition as compared to wild-type mice.

Furthermore, claims 5, 6 and 13 still encompass a cell, and method of using said cell, other than an embryonic stem cell or cell derived from a transgenic animal. The previous office action clearly states that the disclosure is enabling only for a cell derived from a KO mouse (final sentence on page 3). In addition to a cell obtained from the knockout mouse, the disclosure is enabling for an ES cell comprising disruption of the stefin homologue gene comprising the sequence set forth as SEQ ID NO:1, which can be used to make a knockout mouse that, when homozygous for the disruption, expresses a phenotype including hyperactivity, decreased propensity to despair, schizophrenic behavior and decreased prepulse inhibition as compared to wild-type mice. For reasons of record in Paper No. 11, the disclosure is not enabling for any cell other than a cell derived from the transgenic mouse or a mouse ES cell.

Claims 11 and 13 also stand rejected for being directed to a method of identifying an agent that modulates the expression of a stefin homologue in an animal comprising a disruption in the stefin homologue gene by any means other than amelioration of a phenotype associated with homozygous disruption of the stefin homologue gene comprising the sequence set forth as SEQ ID NO:1. As stated in the previous office action, the specification is enabling for “a method of identifying an agent that modulates the expression and/or function of a stefin protease inhibitor gene and *thereby ameliorates a phenotype associated with the disruption*” (page 10,

first full paragraph). The specification does not teach a method by which expression of a gene that has been disrupted can be measured; therefore, for reasons of record in Paper No. 11, claims 11 and 13 stand rejected under 35 U.S.C. § 112, first paragraph.

Finally, claim 10 stands rejected in being directed to a method of producing a transgenic mouse, which comprises in step (a) introducing a targeting construct into any cell other than a mouse embryonic stem cell. As stated in the first full paragraph on page 9 of the previous office action, “[s]ince homologous recombination is required for gene targeting methods such as employed in the instant invention, embryonic stem (ES) cell technology must be available to carry out the method.” Neither the instant disclosure nor the prior art provide enablement for a method of producing a transgenic mouse from any cell other than a mouse ES cell.

Claim Rejections - 35 USC § 112, first paragraph (possession)

Claims 1-11, 13 and 18-26 stand rejected, and new claims 28-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description for the full scope of the claims for the reasons set forth in Paper No. 11.

In response to the rejection, applicant has amended claims 1, 3 and 4 such that they are now directed to a targeting construct “capable of homologous recombination with SEQ ID NO:1”, and claims 5, 8 and 10 such that they are now directed to cells and mice, and methods of producing cells and mice, comprising a “genome comprising a target sequence disrupted by homologous recombination...with a sequence homologous to a region of SEQ ID NO:1”. The amended claims are still directed to products and methods which require possession of a genus of stefin homologue genes which are not adequately described in the disclosure (i.e. any gene other

than the a gene comprising the sequence set forth as SEQ ID NO:1). Therefore, for reasons of record in Paper No. 11, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of genes comprising a sequence *homologous* to a region of SEQ ID NO:1. Therefore, only the described targeting constructs comprising all or a portion of the sequence set forth as SEQ ID NO:1, methods of using said targeting constructs comprising all or a portion of the sequence set forth as SEQ ID NO:1 and mice and cells comprising a disruption of the stefin gene comprising the sequence set forth as SEQ ID NO:1 meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 103

Rejection of claims 1-11, 13 and 18-26 under 35 U.S.C. § 103(a) as unpatentable over Tsui *et al.* and Pennachio *et al.* further in view of Capecchi *et al.* is withdrawn in view of the amendments to the claims and arguments of record in Paper No. 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in being directed to a cell derived from a “non-human transgenic animal”. There is no antecedent basis in claim 8 for any transgenic animal other than a mouse. Amending the claim such that it is directed to a cell derived from the transgenic mouse of claim 8 would overcome this rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
January 10, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER